Appellant's Brief

Application No. 08/928,272 Paper Dated: March 30, 2011

In Reply to USPTO Correspondence of December 6, 2010

Attorney Docket No. 3896-092985 (P-3818)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.

08/928,272

Confirmation No.:

9434

Applicant

Michael J. ISKRA

Filed

*

Title

September 12, 1997

COLLECTION CONTAINER ASSEMBLY

Group Art Unit

3771

Examiner

Kristen Clarette Matter

Mail Stop Appeal Brief - Patents

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Appellant appeals the rejections set forth in the Office Action mailed on December 6, 2010, which reopened prosecution and advanced new rejections in response to an Appeal Brief filed by Appellant on November 22, 2010. This Appeal Brief is submitted in furtherance to the Notice of Appeal electronically filed on March 7, 2011. The Notice of Appeal appeals the rejection of claims 1 and 5-9 advanced in the December 6, 2010 Office Action. The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 41.37. Appellant requests that the previously paid Notice of Appeal fee and Appeal Brief fee be applied to this new appeal.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on March 30, 2011.

Od/30/2011

Date

Signature

Sharyn Beck

Typed Name of Person Signing Certificate

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Response Under 37 C.F.R. § 41.37 Appellant's Brief Application No. 08/928,272 Paper Dated: March 30, 2011 In Reply to USPTO Correspondence of December 6, 2010 Attorney Docket No. 3896-092985 (P-3818)

I. REAL PARTY IN INTEREST

Becton, Dickinson and Company, having its principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417, is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

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II. RELATED APPEALS AND INTERFERENCES

This application (U.S. Patent App. Serial No. 08/928,272) was previously before the Board of Patent Appeals and Interferences in Appeal No. 2005-2410. A Decision on Appeal affirming the Examiner's rejections under 35 U.S.C. §§ 102(b) and 103(a) of the then-pending claims was mailed on September 19, 2005. A copy of this Decision is attached hereto.

There are no other appeals or interferences known to the Appellant, the Appellant's legal representative, or the Assignee of the above-identified application which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

Response Under 37 C.F.R. § 41.37 Appellant's Brief Application No. 08/928,272 Paper Dated: March 30, 2011 In Reply to USPTO Correspondence of December 6, 2010 Attorney Docket No. 3896-092985 (P-3818)

III. STATUS OF THE CLAIMS

Claims 1 and 5-9 are pending in the present application and are the subject of this Appeal. Claim 1 is in independent form. Claims 1 and 5-9 stand rejected under 35 U.S.C. § 103(a) for obviousness based on United States Patent No. 5,458,854 to Burns (hereinafter "the Burns patent" or "Burns") in view of United States Patent No. 4,358,425 to Finney (hereinafter "the Finney patent" or "Finney"). Claims 1 and 5-9 also stand rejected under 35 U.S.C. § 103(a) for obviousness based on United States Patent No. 5,038,958 to Dreier (hereinafter "the Dreier patent" or "Dreier") in view of United States Patent No. 5,422,018 to Saunders (hereinafter "the Saunders patent" or "Saunders") and Finney. Each of these claims has been rejected at least twice. All other claims have been cancelled and are not part of this Appeal.

Response Under 37 C.F.R. § 41.37 Appellant's Brief Application No. 08/928,272 Paper Dated: March 30, 2011 In Reply to USPTO Correspondence of December 6, 2010 Attorney Docket No. 3896-092985 (P-3818)

IV. STATUS OF AMENDMENTS

All amendments previously made to the claims have been entered. The claims have not been amended after being rejected in the December 6, 2010 Office Action. A copy of the claims, as presently pending, is provided in the Claims Appendix attached hereto.

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V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a one piece collection container assembly (50). (See Figs. 3 and 4.) The assembly (50) includes an elongate tubular housing having a sidewall (62) extending between opposed first and second ends. (See Figs. 3 and 4; see also page 4, lines 12-14 and page 8, lines 13-22.) The assembly (50) further includes a solid partition (76) in contact with the sidewall (62). (See FIGS. 3 and 4; see also page 9, lines 3-5.) The solid partition (76) is positioned within the housing between the first end and the second end. (Id.) The solid partition (76) forms a closed bottom. (See FIGS. 3 and 4; see also page 4, lines 14-25 and page 8, line 17 through page 9, line 6.) The housing defines a volume for specimen collection and containment therein between the first end and the partition. (See Figs. 3 and 4; see also page 4, lines 12-14 and page 8, line 24 through page 9, line 5.) The second end forms a false bottom which includes a bottom end that is below the partition. (See FIGS. 3 and 4; see also page 4, lines 14-19 and page 8, lines 19-22.) The bottom end has an annular skirt (78) and a semi-spherical bottom (80) which has an opening (82) therein. (See Figs. 3 and 4; see also page 4, lines 12-14 and page 8, lines 19-22.)

Other than claim 1, there are no other independent claims involved in this Appeal.

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VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Based upon the rejections presented in the Office Action dated December 6, 2010, Appellant presents the following grounds of rejection to be reviewed on Appeal:

- I. Whether claims 1 and 5-9 were properly rejected under 35 U.S.C. § 103(a) for obviousness based upon the Burns patent in view of the Finney patent.
- II. Whether claims 1 and 5-9 were properly rejected under 35 U.S.C. § 103(a) for obviousness based upon the Drier patent in view of the Saunders patent and the Finney patent.

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VII. ARGUMENT

All of the presently pending claims were improperly rejected in the Office Action. In general, the Office Action fails to demonstrate that the combination of the Burns patent and the Finney patent or the combination of the Drier patent and the Saunders and Finney patents would suggest to one skilled in the art a one-piece collection container assembly comprising a solid partition positioned between the first and second ends of a tubular housing where the second end of the housing forms a false bottom with a bottom end comprising an annular skirt and a semi-spherical bottom with an opening therein.

For at least this reason, which is discussed in greater detail hereinafter, Appellant respectfully requests that the Board overturn the rejections of the Examiner, and remand this matter to the Examiner with instructions to reopen prosecution and allow the currently pending claims.

I. CLAIMS 1 AND 5-9 WERE IMPROPERLY REJECTED UNDER 35 U.S.C. 103(a) FOR OBVIOUSNESS BASED ON BURNS AND FINNEY

Claims 1 and 5-9 stand rejected under 35 U.S.C. § 103(a) for obviousness based on the Burns patent in view of the Finney patent. In view of the following remarks, Appellant respectfully requests reversal of this rejection.

A. The Scope and Content of the Prior Art

1. The Burns Patent

The Burns patent is directed to a collection assembly (10) comprising a container (12) and a cap (14). The container (12) has a sidewall (22) that extends from an upper portion (28), which includes an open end (31), to a lower portion (30), which includes a closed bottom end (38) and an annular skirt (37) extending from the closed bottom end. The cap (14) has an annular outer skirt (58) and an inner annular inverted recessed skirt portion (64). The annular skirt (37) of the collection assembly (10) "provides a means for allowing the container to be placed on a flat surface." (Burns, col. 3, lines 52-53.) Particularly, "[w]hen the cap is positioned on the bottom of the container during fluid collection, the cap provides a means for allowing the container to be placed upright on a flat surface." (Burns, col. 5, lines 9-12; *see also* FIG. 6.) The Page 9 of 27

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collection assembly in Burns is for use in collecting small quantities of blood in a secure fashion for subsequent testing. (Burns, col. 1, lines 10-14.) The collection assembly is purported to be particularly useful in micro-centrifuges. (Burns, col. 2, lines 43-44.) The disclosed advantages of the Burns collection assembly include, *inter alia*, that radial spray of excess fluid is minimized, that the cap can be secured and unsecured to the annular space in the skirt at the bottom of the cap, and that the rim of the cap can substantially prevent contamination to the specimen inside the container when the cap is secured to the container. (Burns, col. 2, line 49 through col. 3, line 7.)

2. The Finney Patent

The Finney patent is directed to a centrifuge tube which is useful for obtaining analytical samples. (Finney, col. 1, lines 5-8.) The centrifuge tube (10) of Finney has a rounded bottom (12) containing a passageway (14). (Finney, col. 2, lines 17-19.) A recess (16) co-axial with the passageway (14) is provided on the inner side of the tube (10) and another recess (18) also co-axial with the passageway (14) is provided on the outer side of the tube (10). (Finney, col. 2, lines 19-22.) A tight fitting, resilient plug (20) is disposed in the passageway (14), and the plug (20) provides a leak-tight closure for the passageway (14) and the recesses (16, 18). (Finney, col. 2, lines 26-35.) The plug (20) is pierceable by a hypodermic syringe (26). (Finney, col. 2, line 39.) This centrifuge tube arrangement allows for a sedimentation fraction that has accumulated at the bottom of the tube to be removed through the bottom of the tube (rather than through the top of the tube) by piercing the plug with the needle of the hypodermic syringe and drawing out the fraction which has settled at the bottom of the tube. (Finney, col. 2, lines 36-41.) Finney states "[i]n this way, the constituents of a desired strata may be withdrawn from the tube without having it remix with adjacent layers." (Finney, col. 2, lines 41-43.) Finney proffers that this apparatus satisfied a need in the art for a puncturable-bottom centrifuge tube which is transparent and which can withstand forces in the region of 150,000 G's. (Finney, col. 1, lines 56-59.) Finney is clearly not directed to a false-bottomed container, despite the assertions in the Office Action to the contrary.

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B. The Flat Bottom Edge of the Burns Patent is Clearly Distinct from the Semi-Spherical Bottom with an Opening Therein of Claim 1

Independent claim 1 defines a one piece collection container assembly comprising an elongate tubular housing. With respect to the elongate tubular housing, claim 1 recites, in relevant part, "said second end [of the elongate tubular housing] forming a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein." (emphasis added).

The Examiner asserts that Burns discloses a one piece collection container assembly having an elongate tubular housing (12) having opposed first and second ends (as shown in Fig. 2), a solid partition (38) contacting a sidewall (22) of the tube forming a closed bottom (38) and positioned within said housing between the first and second ends (as shown in Fig. 2). The Examiner further contends that the housing defines a volume for specimen collection and containment therein between the first end and said partition, the second end forming a false bottom having a bottom end below the partition having an annular skirt (37) having an opening (47) therein. The Examiner recognizes, however, that Burns does not disclose that the bottom of the tube is semi-spherical. This recognized deficiency in Burns is confirmed by reference to, for instance, Figures 1, 2, 5 and 6 of Burns, each of which shows a container having a flat bottom edge (47) formed from the annular skirt (37) which provides a means for allowing the container to be placed upright on a flat surface. (Burns, col. 3, lines 48-53.)

Thus, there exists a clear and recognized difference between the claimed design and the design disclosed in Burns. Specifically, where the container in the Burns patent has a flat bottom edge, the bottom end of the claimed collection container comprises a semi-spherical bottom with an opening therein.

C. The Asserted Reasons for Modifying Burns do not Support a Finding of Obvious

Despite the recognized differences between what is taught in Burns and what is recited in claim 1, the Examiner concluded that the claims do not define over the prior art. In particular, the Examiner asserted that it would have been obvious, in view of Finney, to modify

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Burns to include a bottom edge that is semi-spherical. However, the rationale provided to support this conclusion is insufficient to establish a *prima facie* case of obviousness and inconsistent with the actual teachings of the cited art. Therefore, the rejection under 35 U.S.C. § 103(a) is improper and should be reversed.

First, in the paragraph bridging pages 3 and 4 of the Office Action, the Examiner concludes that modifying the bottom end of the tube in Burns so that it is semi-spherical is "an obvious design consideration" that does not patentably distinguish over the prior art. The proffered rationale justifying this conclusion is that "[c]hanging the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube." The Examiner attempts to support this conclusion by asserting that Finney, and more particularly the abstract of Finney, discusses how such a semi-spherical shape allows the tube to be used in the cavity of a centrifuge rotor.

However, the Finney patent does not support the conclusion that it would be obvious to change the bottom of the Burns container to have a semi-spherical shape. The abstract of Finney, which is cited by the Examiner, is reproduced in its entirety below:

A transparent tube for use in the cavity of the rotor of a high speed centrifuge. The tube is penetrable at its bottom end by a needle of a hypodermic syringe. The tube is open at the top and has a rounded bottom with an opening forming a passageway therein. A recess forming a shoulder co-axial with the passageway is provided both on the inner side and the outer side of the tube. A resilient plug having flanges at each end provides a tight fitting closure for the passageway and recesses.

There is nothing in this passage that suggests, let alone teaches, that the shape of the bottom of the tube is what allows the tube to be useable in the cavity of a centrifuge rotor. The statement regarding the use of the tube in the cavity of the rotor and the separate statement that the tube has a rounded bottom are independent from one another, and together do not imply that only rounded bottom tubes can be used in a centrifuge. In other words, just because the tube is used in a centrifuge and has a rounded bottom, it does not necessarily follow that tubes not

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having a rounded bottom could not be used in a centrifuge. Indeed, the preferable use of the container in the Burns patent, which does not have a rounded bottom, is in a micro-centrifuge (Burns, col. 2, lines 43-44) or, with the aid of a flat-bottomed extension, in a normal centrifuge. (Burns, col. 5, lines 13-17.)

Finney discusses the prior art centrifuge tube with a penetrable bottom of United States Patent No. 3,875,012 to Dorn. Finney describes the Dorn tube as being "essentially a right circular cylindrical closed by a resilient stopper at each end." (Finney, col. 1, lines 46-47.) Finney states that the Dorn tube is unsuited for use at forces above 6,000 G's because the straight-sided design that is employed by Dorn cannot withstand high forces without leaking. (Finney, col. 1, lines 49-55.) However, this is not a justification for modifying false bottom containers, like those taught in Burns and defined in claim 1, because these false bottom containers are not designed to carry a liquid in the false-bottomed portion, as evidenced by the fact that they include an opening in the bottom thereof. Therefore, one skilled in the art reading Finney's suggestion that a rounded bottom be used to avoid leaks at high centrifugal speeds would not find this discussion relevant with respect to false bottom containers since this design would not provide any advantage to such a false bottom container. Moreover, the fact that Finney discusses Dorn's right circular cylinder centrifuge tube without any mention that this shape is not compatible with common standard centrifuge equipment further rebuts the Examiner's position that Finney teaches that a rounded bottom shape allows the tube to be used in the cavity of a centrifuge rotor.

Considering the actual teachings of Finney, the Examiner's conclusion that a tube with a rounded bottom allows for compatibility with clinical equipment appears to be based not on Finney, but rather on the specification of the subject application itself. Indeed, the subject specification states that a "further advantage of the assembly of the present invention is that it provides a specimen collection container which is universally compatible with various clinical equipment and instrumentation." (Specification, page 5, lines 21-26.) Of course, it axiomatic that the obviousness determination cannot be based on knowledge gleaned from applicant's disclosure but must instead be based on the state of the art at the time the subject application is

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filed. *In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Thus, this rationale fails to support a finding of obviousness.

The Examiner, on page 4 of the final Office Action, also contends that Finney discloses a specimen collection tube with a rounded, semi-spherical false bottom. However, this is incorrect as Finney fails to disclose or suggest a specimen collection tube with a rounded, semi-spherical false bottom. Instead, Finney discloses a centrifuge tube (10) containing a passageway (14) and a tight fitting, resilient plug (20) disposed in the passageway (14) which provides a leak-tight closure for the passageway (14). (Finney, col. 2, lines 26-35.) The plug (20) is pierceable by a hypodermic syringe (26). (Finney, col. 2, line 39.) There is nothing in Finney which could even be arguably identified as a false bottom. Simply put, Finney fails to disclose or suggest a false bottom portion. Thus, the Examiner is incorrect in this regard as well.

Stripping away these inaccurate representations concerning the teachings of the Finney patent, the Examiner is left with the conclusion that changing the shape of the Burns design to make it semi-spherical constitutes an "obvious" design consideration. However, this statement simply assumes what it purports to explain. Namely, why, based on evidence of record, it would be obvious to modify the Burns design to include a semi-spherical bottom end. Such unsupported and unreasoned rejections are exactly the type the Federal Circuit and Supreme Court have warned against. See In re Kahn, 78 USPQ.2d at 1336 ("rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."); see also KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 415, 82 USPQ.2d 1385, 1396 (2007) (quoting Federal Circuit statement from Kahn with approval). Therefore, this rationale fails to support a prima facie case of obviousness.

Appellant further submits that Burns specifically <u>requires</u> that the bottom end of the tube includes a cylindrical shape for receiving a portion of the cap thereon. As recited in Burns at column 5, lines 7-12, "As shown in Fig. 6, cap 14 is readily compatible with skirt 37 on the lower portion of the container. Space 68 of the cap receives the skirt of the container. When the cap is positioned on the bottom of the container during fluid collection, the cap provides a means for allowing the container to be placed upright on a flat surface" (emphasis added).

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Accordingly, the bottom of the tube of Burns is cylindrical to allow the cap to be engaged therewith to provide a means for allowing the container to be placed on a flat surface during fluid collection. Burns is entirely silent as to: 1) that the bottom end of the tube is semi-spherical; and 2) that the bottom of the tube is adapted for common instrument compatibility.

Indeed, modifying the bottom end of the Burns collection tube to include a semispherical shape could destroy one of the advantages of the Burns design, namely that the bottom end of the tube can accept the cap portion. The comments by the Examiner on page 8 of the Office Action that the Burns tube, as modified, could stand upright through the use of a stand or by modification of the cap ignores the fact that Burns explicitly teaches that one intended purpose of the container design is to allow the container to stand upright on a flat surface, without a need for any such separate stand. There is also absolutely nothing in Burns suggesting that the cap could or should be modified to fit a round bottom container. As the MPEP reminds "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01, subpart II (citing In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).) The Examiner cannot use the claims as a blueprint for locating separate claim elements in separate prior art references without considering the teachings of the prior art as a whole and without considering the complete teachings of the separate references. In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999); See also In re Wesslau, 353 F.2d 238, 241 (CCPA 1965) ("It is impermissible...to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). Thus, the proposed modification of Burns fails to consider the Burns patent as a whole, including the teachings away of a container having a semi-spherical bottom.

Significantly, it is further noted that the Drier patent (discussed *infra*), which the Examiner also cites as allegedly teaching a false bottom container, similarly discusses the importance of a flat-bottomed, cylindrical outer shell to allow the tube to stand upright on a flat surface. In other words, of the two patents which the Examiner cites as disclosing false bottom

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containers, <u>both of these patents explicitly extol the virtues of a flat-bottomed, cylindrical outer shell, and thereby teach away from the semi-spherical design of the claimed invention.</u>

Thus, neither Burns, nor Finney, nor the combination of Burns and Finney, disclose or suggest a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein, as recited by Appellant's claim 1. Appellant further submits that neither Burns nor Finney provide a motivation or reason for a worker in the art to modify Burns to include a semi-spherical bottom. In fact, Burns expressly teaches away from the inclusion of a semi-spherical bottom for the reasons discussed herein. Therefore, the rejection of claims 1 and 5-9 as obvious over Burns in view of Finney is improper and should be reversed.

II. CLAIMS 1 AND 5-9 WERE IMPROPERLY REJECTED UNDER 35 U.S.C. 103(a) FOR OBVIOUSNESS BASED ON DRIER IN VIEW OF SAUNDERS AND FINNEY

Claims 1 and 5-9 stand finally rejected under 35 U.S.C. § 103(a) for obviousness based on the Drier patent in view of the Saunders and Finney patents. In view of the following remarks, Appellant respectfully requests reversal of this rejection.

A. The Scope and Content of the Prior Art

1. The Drier Patent

The Drier patent is directed to a sealable vented microscale centrifuge tube for centrifuging samples. (Drier, Abstract.) The tube (10) includes a container (11), a shell (12) and a flange (14) which is attached to both the container (11) and the shell (12). (Drier, col. 2, lines 36-38; *see also* Fig. 1.) The container (11) forms a cavity (16) having an open end (18) and a closed end, and the flange (14) is located at the open end of the cavity (16). (Drier, col. 2, lines 39-41.) The flange (14) has a hole (20) formed therethrough. (Drier, col. 2, lines 41-42.) The purported advantage of the hole (20) is to allow air which would otherwise be compressed when the tube is stoppered to be vented, avoiding pressure buildup in the container that occurs upon stoppering. (Drier, col. 1, lines 21-26 and col. 1, line 68 – col. 2, line 4.) The shell (12) has a first open end (24) and a second open end (26), surrounds the length of the container (11) and is Page 16 of 27

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coupled to the container (11) by the flange (14). (Drier, col. 2, lines 45-49.) The shell (12) is preferably cylindrical in shape, and extends at least as long as the container in order to allow the second open end (28) of the shell (12) to support the tube (10) in an upright position on a flat surface such as a laboratory bench. (Drier, col. 2, lines 60-68.) The ability of the tube to stand upright on a flat surface is an important consideration in the Drier patent. Indeed, in the Summary of the Invention, Drier provides that "[a]nother feature of the invention is that the microcentrifuge tube is capable of standing upright on a flat surface without a separate support such as a tray or rack, and thus facilitates handling and loading of samples on the microscale level." (Drier, col. 1, lines 48-52.)

2. The Saunders Patent

The Saunders patent is directed to a centrifuge tube and adaptor apparatus which facilitates separation of biological materials and permits easy extraction of a fraction after centrifugation. (Saunders, Abstract.) Figure 1 of Saunders shows the tube (2) comprising an hour glass shape with a narrow connecting channel (4) together with larger upper (6) and lower (8) chambers (Saunders, col. 3, lines 60-65.) The lower chamber (8) is sealed at the bottom while the upper chamber (6) is open to allow for samples to be loaded into the tube (2). (Saunders, col. 4, lines 3-6.) During centrifugation, the tube (2) can be housed within an outer vessel (10) which contains an adapter comprising a liquid medium (12). (Saunders, col. 4, lines 9-11.) In other words, a liquid is disposed in the space between the inner wall of the outer vessel (10) and the outer wall of the tube (2). The liquid medium (12) supports the narrow channel (4) and annular connecting segment (7) of the tube (2) in order to prevent tube deformity or collapse at high centrifugation speed. (Saunders, col. 4, lines 15-18.) Saunders also mentions that the outer vessel (10) may be the aperture or cavity of the centrifuge rotor itself, such that a liquid medium is contained within the cavity. (Saunders, col. 4, lines 50-53.)

3. The Finney Patent

The Finney patent is discussed *supra*, the discussion of which is incorporated herein by reference.

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B. The Flat Bottom Edge of the Drier Patent is Clearly Distinct from the Semi-Spherical Bottom with an Opening Therein of Claim 1

Independent claim 1 defines a one piece collection container assembly comprising an elongate tubular housing. With respect to the elongate tubular housing, claim 1 recites, in relevant part, "said second end [of the elongate tubular housing] forming a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein." (emphasis added).

The Examiner asserts that Drier discloses a one piece collection container assembly having an elongate tubular housing (12) having opposed first and second ends (as shown in Fig. 2), a solid partition (11) contacting a sidewall of the tube (as shown in Fig. 2) forming a closed bottom (col. 3, lines 5-10) and positioned within said housing between the first and second ends (as shown in Fig. 2). The Examiner further contends that the housing defines a volume (16) for specimen collection and containment therein between the first end and said partition (Abstract and col. 3, lines 5-10), said second end forming a false bottom comprising a bottom end below the partition (Figures 1 and 2 and col. 2, lines 65-68) comprising an annular skirt with an opening therein (Figs. 1 and 2). However, the Examiner recognizes that, like with Burns discussed *supra*, Drier does not disclose that the bottom of the tube is semi-spherical. This recognized deficiency in Drier is confirmed by reference to, for instance, Figures 1-3 thereof, each of which shows a tube having a flat bottom edge (26) formed from the cylindrical shell (12) which provides a means for allowing the tube to stand upright on a flat surface without a separate support. (Drier, col. 1, lines 48-52.)

Thus, there exists a clear and recognized difference between the claimed design and the design disclosed in Drier. Specifically, where the tube in the Drier patent has a flat bottom edge, the bottom end of the claimed collection container comprises a semi-spherical bottom with an opening therein.

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C. The Asserted Reasons for Modifying Drier do not Support a Finding of Obvious

Despite the differences between the tube in Drier and the container defined in claim 1 acknowledged in the Office Action, the Examiner concluded that the claims do not define over the prior art because it would have been obvious, in view of Saunders and Finney, to modify Burns to include a bottom edge that is semi-spherical. However, the Examiner's rationale fails to support this conclusion and it is inconsistent with the actual teachings of the cited art. Therefore, the rejection under 35 U.S.C. § 103(a) is improper and should be withdrawn.

In the first full paragraph on page 6 of the Office Action, the Examiner asserts that Saunders discloses that centrifuge tubes are typically "flat or slightly rounded" and that Finney "likewise" discloses a centrifuge tube with a rounded, semi-spherical false bottom. The Examiner concludes, based on these two statements, that it would have been obvious to one of ordinary skill in the art to have rounded the bottom end of Drier as taught by Finney in order to allow the tube to work with "typical" laboratory equipment as taught by Saunders.

The quoted statement from Saunders that centrifuge tubes are typically "flat or slightly rounded," when viewed in context, as it would be viewed by one skilled in the art considering the Saunders patent, does not support the conclusion that the bottom end of the Drier tube should be rounded as the Examiner argues. Saunders is directed to centrifuge tubes and adapters for separation of biological materials. (Saunders, col. 1, lines 4-5.) While the Examiner is correct that the Background of the Invention section of Saunders states that centrifuge tubes are "typically cylindrical with a flat or slightly rounded bottom," this statement is immediately followed by stating that "[t]he shape of the walls of the centrifuge tube imparts separation characteristics to the sample within the tube." (Saunders, col. 1, lines 14-18.) In other words, Saunders suggests that the shape (i.e. flat or slightly rounded) of the tube affects the ability of the tube to separate biological materials, which is consistent with the focus of the Saunders patent. However, Drier is directed to a false bottom tube. Because of this, the shape of the wall at the bottom would have no impact on the "separation characteristics" of the tube because no material for separation is contained in the false bottom portion of the container. This is clear from the

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figures of Drier which unequivocally show an open bottom end. One skilled in the art would therefore not find in this statement in Saunders any reason to modify the flat bottom of the tube described in the Drier patent since the separation characteristics of the bottom section of the Drier false bottom tube are irrelevant.

Appellant again notes that both Finney and Burns disclose the concept of flatbottomed tubes being used in common laboratory equipment, including, without limitation, in centrifuge machines. This is also true of the Drier patent, titled "Vented Microscale Centrifuge Tube," which is clearly limited to a flat-bottomed tube. Thus, the Examiner's assertion that the prior art teaches that using a tube having a rounded bottom is needed to allow the tube to work with typical laboratory equipment is contrary to the evidence of record.

The Examiner, on page 6 of the final Office Action, again contends that Finney discloses a specimen collection tube with a rounded, semi-spherical false bottom. However, this is incorrect as Finney fails to disclose or suggest a specimen collection tube with a rounded, semi-spherical false bottom. Instead, Finney discloses a centrifuge tube (10) containing a passageway (14) and a tight fitting, resilient plug (20) disposed in the passageway (14) which provides a leak-tight closure for the passageway (14). (Finney, col. 2, lines 26-35.) The plug (20) is pierceable by a hypodermic syringe (26). (Finney, col. 2, line 39.) There is nothing in Finney which could be arguably identified as a false bottom. Simply put, Finney fails to disclose or suggest a false bottom portion. Thus, the Examiner is incorrect in this regard as well.

The Examiner's conclusion that one skilled in the art would be motivated to change the flat bottom of the Drier tube to a semi-spherical shape in order to allow the tube to work with typical laboratory equipment is not based on any reasoning or other rationale culled from Finney and Saunders. Instead, this conclusion appears to be pulled directly from the specification of the subject application itself. Indeed, the subject specification states that a "further advantage of the assembly of the present invention is that it provides a specimen collection container which is universally compatible with various clinical equipment and instrumentation." (Specification, page 5, lines 21-26.) Of course, it axiomatic that the obviousness determination cannot be based on knowledge gleaned from applicant's disclosure

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but must instead be based on the state of the art at the time the subject application is filed. *In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Thus, this rationale fails.

Appellant further submits that Drier teaches away from an arrangement where the bottom end of the tube is rounded. As recited in Drier at column 1, lines 48-52, "[a]nother feature of the invention is that the microcentrifuge tube is capable of standing upright on a flat surface without a separate support such as a tray or rack, and thus facilitates handling and loading of samples on the microscale level." Drier repeats this sentiment at least two other times in the application, at column 2, lines 12-14 and at column 2, lines 64-68. As Drier makes clear, the bottom of the tube is cylindrical to allow the tube to be placed on a flat surface. Drier is entirely silent as to any suggestion that the bottom of the tube be semi-spherical (or any shape other than flat for that matter) or that the bottom of the tube should be rounded to fit typical centrifuge equipment. This is true despite the fact that the Drier tube is clearly intended for use in a centrifuge, as evidenced by the title of the patent, "Vented Microscale Centrifuge Tube." Modifying the bottom end of the Drier tube to include a semi-spherical shape could destroy one of the disclosed advantages of the Drier design, namely that the tube can easily stand upright on a flat surface without a separation support. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01, subpart II (citing In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).) The Examiner cannot use the claims as a blueprint for locating separate claim elements in separate prior art references without considering the teachings of the prior art as a whole and without considering the complete teachings of the separate references. In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999); See also In re Wesslau, 353 F.2d 238, 241 (CCPA 1965) ("It is impermissible...to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."). Thus, the proposed modification of Drier fails to consider the Drier patent as a whole, including the teachings away of a tube having a semi-spherical bottom.

To the extent the Examiner contends, on page 6 of the Office Action, that Drier would perform equally well with any known shape ignores these clear teachings regarding the Page 21 of 27

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advantages of the flat bottom repeatedly mentioned in Drier. Moreover, this conclusory statement is wholly supported by any evidence.

Appellant again notes that both of the patents cited by the Examiner as disclosing a false bottom container (Burns and Drier), which is also the subject matter of claim 1, are limited to tubes having flat bottoms. Moreover, the flat bottom feature discussed in each of these patents is an important and significant feature of the design. Thus, one skilled in the art modifying the flat bottom tubes of Burns or Drier to have a semi-spherical bottom would have to disregard the clearly defined advantages of the flat bottom design disclosed in both of the primary references.

Thus, Drier, whether viewed alone or in combination with Saunders and Finney, fails to disclose or suggest a false bottom container where said bottom end comprises an annular skirt and a semi-spherical bottom with an opening therein, as recited by Appellant's claim 1. Appellant further submits that neither Drier nor Saunders or Finney provides a motivation or reason for a worker in the art to modify Drier to include a semi-spherical bottom. In fact, Drier expressly teaches away from the inclusion of a semi-spherical bottom for the reasons discussed herein. Therefore, the rejection of claims 1 and 5-9 as obvious over Drier in view of Saunders and Finney is improper and should be reversed.

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VIII. CONCLUSION

For the reasons set forth above, Appellant submits that claims 1 and 5-9 are indeed patentable over the cited art and are in condition for allowance. Reversal of all of the Examiner's rejections and remand of this case to the Examiner are respectfully requested.

Appellant's fee of \$540.00 paid on November 22, 2010 in connection with the submission of an Appeal Brief on that date is believed to cover the fee required for submission of this Appeal Brief, and thus no fee is believed to be due. However, the Commissioner of Patents and Trademarks is hereby authorized to charge any additional fees which may be required to Deposit Account Number 23-0650. Please refund any overpayments to Deposit Account Number 23-0650.

Respectfully submitted,

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CLAIMS APPENDIX

1. A one piece collection container assembly comprising:

an elongate tubular housing having a sidewall extending between opposed first and second ends; and

a solid partition in contact with said sidewall, positioned within said housing between said first and second ends, forming a closed bottom;

said housing defining a volume for specimen collection and containment therein between said first end and said partition;

said second end forming a false bottom comprising a bottom end below said partition, said bottom end comprising an annular skirt and a semi-spherical bottom, wherein said semi-spherical bottom comprises an opening therein.

- 5. The assembly of Claim 1, wherein said partition is arcuate in shape to provide said volume for specimen collection with at least a partially rounded bottom portion.
 - 6. The assembly of Claim 1, wherein said partition is conical in shape.
- 7. The assembly of Claim 1, wherein said housing is a thermoplastic polymer.

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8. The assembly of Claim 7, wherein said thermoplastic polymer is polyethylene terephthalate, polypropylene, polyethylene napthalate, polyvinyl chloride or copolymers thereof.

9. The assembly of Claim 1, wherein said housing comprises an outer diameter, a length and an internal volume, wherein said outer diameter is about 13 to about 16 millimeters, said length is about 75 to about 100 millimeters and said internal volume is about 1 to about 3 milliliters.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

1. Copy of the Decision on Appeal of Appeal No. 2005-2410, mailed September 19, 2005, concerning United States Patent Application No. 08/928,272.